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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,918	11/08/2000	Julia J. Dibner	NVI-5009.1	2670

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SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/708,918	DIBNER ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 9-30-03 has been entered into the record. Claims 55-75 are pending. Claims 55-75 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The objection to the specification is withdrawn in view of Applicant's previously submitted amendment which has now been entered into the record.

Information Disclosure Statement

The information disclosure statement filed 7/03 has been considered. See attached initialed copies.

Rejections Maintained

Art Rejections

Claims 55-60 and 66-70 stand rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al (WO 96/40233, published 12 December 1999) is maintained for reasons made of record in the previous office action of record mailed 5-30-03.

Applicant's arguments have been carefully considered but are not persuasive. Applicant argues that amended claim 55 provides that the oocytes containing the live sporocysts have been separated by tangential flow filtration from an aqueous composition containing bacterial or fungal contaminants. Applicants argue that the contaminants that may be removed are sugars or sanitizing agents. As such, the contaminants referenced in claim 55 may be a variety of viable and non-viable contaminants and as such the oocysts of claim 55 are separated from the aqueous composition by tangential flow filtration, fewer contaminants are present in the final preparation. This is not persuasive, the methods of

the prior are provide for substantial repeated washing and centrifugation to remove contaminants (see page 6 of Evans et al) and multiple agents having in inhibitory or killing effect for bacterial, viruses and fungal agents. Postassium dichromate is known in the art in this process to serve several purposes including its antibacterial, antifungal and antiviral agent. The argument alleges a "purer" preparation however it provides no intrinsic or extrinsic evidence thereof. Applicants statement of a purer preparation by tangential flow filtration is unsupported by documented evidence and is conjecture and ignores the repeated wash steps of Evans to remove the sanitizing agents etc. Applicants argue that sanitation with sodium hypochlorite does not remove non-viable contaminants. This is not persuasive, Evan et al teach multiple rounds of centrifugation and resuspension in deionized or distilled water or saline to remove these contaminants and sporulating agents. These multiple washing steps would remove non-viable contaminants. Applicant's arguments are not supported by the methods of Evans et al. Applicants have provided no side-by side comparison of the composition of the art and the instantly claimed composition and evaluated the purity thereof and the arguments are limited to conjecture. The arguments are not persuasive, there is no showing that the process of multiple washings, centrifugations and density gradient separation would not achieve the same final composition. Applicant continues to argue the process limitation of tangential flow filtration, however, no intrinsic or extrinsic evidence is provided that the final product of the two composition are different in alleged contaminants. Applicants allegations are unsupported by extrinsic evidence. Applicant argues that the presence of non-viable contaminants "may" result in pyrogenic reaction. This is again conjecture. There is no comparison of the pyrogenicity of the production of the prior art and that of the instantly claimed composition. Further, in this specification there is no teaching of reduced pyrogenicity as compared to the art or reduced pryogen content. Applicant continues to argue minute differences in the preparation methods and the hypothetical introduction of contaminants, without any evidence to proffered to support. This again remains not

persuasive, the final product is compared to the final product. There is no comparison of the final product to the final product. Applicants allege that the levels of "possible contamination" are different because the methods to produce the products are different. Again this is an unsupported allegation. It is noted that Applicants method is not a sterile process, does not provide for single component composition. Applicants own specification does not teach that it is free from bacterial, viral or fungal contamination or any other contamination just that it can be tested. Applicants allege that Evans teaches away from sanitizing sporocyts that have been released. This is not persuasive, Evens et al does not teach that sporocyts can not be sanitized. Evans et al does not teach away from such as alleged. Applicants argue that since the claims require the sporocyts to be sanitized. This is not persuasive, it is clear from claim 55 "wherein the cocciodial protozoa are sanitized". As such, Applicants are arguing a process limitation not in the claim 55-65. As to claims 66-75, the product is no different from the product of the prior art. Sanitization is not sterilization and there is no indication that the process of Evans et al results in a product that is more contaminated than the instant process. Applicants argue that the process provides for reduced contamination of viable organisms as compared to Evans et al, but provides no evidence thereof. There is no evidence of any difference in contamination content between the product made by the prior art process and the product made by the claimed process. Applicants rely upon the hypothetical ("may") and fail to provide evidence to support the hypothetical. Applicant argues that Evans et al does not disclose the particular combination of *E. tenella, E. maxima* and *E. acervulina* as called for in claims 58 and 80. This is not persuasive, Evans et al teach any and all combination of two or more species of *E. tenella, E. acervulina, E. maxima, E. necatrix, E. mitis, E. praecox and E. brunetti*. Evans et al teach all combinations of at least two, up to and including all of the listed species (see Evans page 4, lines 9-12). As such, the combination as recited is anticipated by Evans et al. Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although

produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). A similar issue was decided in Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). In Gray, the prior art disclosed human nerve growth factor (b-NGF) isolated from human placental tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different. Applicants are directed to MPEP 2113.

The rejection is maintained.

Claims 61, 62, 64, 71, 72 and 74 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (WO 96/40233; published 12 December 1999) in view of MacDonald et al (U.S. Patent No. 5,055,292, issued October 8, 1991) is maintained for reasons made of record in the previous office action of record mailed 5-30-03.

Applicant's arguments have been carefully considered but are not persuasive. Applicant argues that since Evans et al fails the combination over Evans et al fails. As Evans et al is maintained above, so is the combination over Evans et al. Applicants again argue that since tangential flow filtration is not used and that the sporocysts are not sanitized, there "may" ultimately be have non-viable contaminants. Again, this argument is not persuasive for reasons set forth supra for Evans et al. Again, Applicant argues method steps in a product claim. Again, these arguments are not persuasive, there is no

evidence of record that compares the two compositions such that the statement of Applicant is in fact true. While the composition "may" have more non-viable contaminants, the composition "may not" have more non-viable contaminants. Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (The prior art disclosed human nerve growth factor (b-NGF) isolated from human placental tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different. As discussed above Evans et al does not teach away from sanitizing sporocysts. Applicants argue that Evans et al does not disclose the particular combination of E. tenella, E. maxima and E acervulina as called for in claims 58 and 80. This is not persuasive, Evans et al teach any and all combination of two or more species of *E. tenella, E. acervulina, E. maxima, E. necatrix, E. mitis, E. praecox and E. brunetti.* Evans et al teach all combinations of at least two, up to and including all of the listed species (see Evans page 4, lines 9-12). As such, the combination as recited is anticipated by Evans et al.

Applicant admits that MacDonald et al teaches that oocysts may be treated after sporulation to avoid contamination by other microorganisms. Evans et al teach that their

sporocysts can be made by any conventional method in the art. MacDonald et al was art at the time of Evans et al. As such, the sanitization of sporulated oocysts is and was conventional in the art and Evans et al does not teach away from such but encompasses such methods of art. Applicants argue however, the MacDonald et al do not provide for tangential flow filtration. This is not persuasive, again Applicants are directed to the treatment of product by process limitations in a product claim. Products made by other methods can anticipate or render the claimed composition obvious. Applicant are again attempting to rely upon process limitations and have proffered no evidence of reduced contamination of viable or non-viable components in the vaccine preparation (see MPEP 2113). Applicants argue that MacDonald fails because it fails to teach the process steps lacking in Evans et al. Again this is not persuasive, the claims are drawn to products. Applicant has proffered no evidence indicating that the assertion that the composition "may" have less viable or non-viable contaminants is in fact true. Applicants fail to argue the particular combination as set forth by the examiner. MacDonald et al was cited to teach the suspension of live coccidial vaccines in sterile distilled water, a suspending agent and a preservative to inhibit contamination as set forth in claims 61, 62, 64, 71, 72 and 74.

The rejection is maintained.

Claims 63, 65, 73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (WO 96/40233; published 12 December 1999) and MacDonald et al (U.S. Patent No. 5,055,292, issued October 8, 1991) as applied to claims 61, 62, 64, 71, 72 and 74 above and further in view of Thaxton (U.S. Patent 5,311,841; issued may 17, 1994) is maintained for reasons made of record in the previous office action of record mailed 5-30-03.

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that since the combination of Evans et al and MacDonald et al fail, so does the combination of these teachings with Thaxton et al because Thaxton et al does not teach

the process steps. Applicants again argue specific process limitations and fail to argue the vaccine combination as particularly set forth by the examiner. With respect to the process limitations, these arguments have been fully addressed in the previous rejections *supra*. These arguments, lacking extrinsic evidence to support the alleged (i.e. may have reduced) contamination levels remain unpersuasive.

The rejection is maintained.

New Rejections Based on Amendment

Claims 55-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification lacks conception of sanitization of coccidial protozoa. While the specification provides support for sanitization of the particular life stage of oocysts and sporocysts as pointed to by Applicant in the response, it does not provide written description of sanitization of the coccidial protozoa *per se*. This issue is best resolved by Applicants pointing to the specification by page and line number where sanitization of coccidial protozoa is contemplated.

Status of Claims

All claims stand rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patricia A. Duffy

Primary Examiner

Art Unit 1645